UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,927	12/23/2004	Helmut Fiebig	MERCK-2966	8085

23599 7590 05/03/2010

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
ROONEY, NORA MAUREEN	
ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
05/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

Office Action Summary	Application No.	Applicant(s)	
	10/518,927	FIEBIG ET AL.	
	Examiner	Art Unit	
	NORA M. ROONEY	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,15,16,21,22,26,30,31,33,35 and 36* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13, 15, 21-22, 26, 30-31, 33 and 35-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response filed on 12/28/2009 is acknowledged.

2. Claims 1-13, 15-16, 21-22, 26, 30-31, 33 and 35-36 are pending.

3. Claims 1-12 and 16 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/29/2007.

4. Claims 13, 15, 21-22, 26, 30-31, 33 and 35-36 are currently under examination as they read on a polypeptide encoded by the nucleic acid sequence of SEQ ID NO:1 and a pharmaceutical composition thereof.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 21-22 and 30-31 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for: recombinant, isolated polypeptides of SEQ ID NO: 2, 4, 6 encoded by SEQ ID NO:1, 3 or 5, respectively, the variants of SEQ ID NO:2 in clones 1-11, the polypeptide fragments 1-200 and 185-500 thereof and a composition thereof, does not reasonably provide enablement for: an **immunomodulatory, T-cell-reactive polypeptide fragment which comprises a partial sequence of 50 to 350 amino acids** of the polypeptide sequence (set forth in of claim 13) of claim 21; a polypeptide fragment which **comprises** amino acids 1-200 or amino acids 185-500 of the polypeptide sequence set forth in SEQ ID NO: 2, SEQ ID NO:4, SEQ ID NO: 6 or a polypeptide variant of the sequence set forth in SEQ ID NO: 2 with the amino acid variations set forth in clones 1 to 11 of claim 22 and a **pharmaceutical composition** comprising at least one polypeptide according to Claim 21 or Claim 22 of Claims 30-31. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the invention commensurate in scope with these claims for the same reasons as set forth in the Office Action mailed on 09/25/2009.

Applicant's arguments filed on 12/28/2009 have been fully considered, but are not found persuasive.

Applicant argues:

"Applicants' claims are now directed to polypeptide molecules and fragments thereof comprising specific sequences. Variants of the claimed molecules, comprising, for example, the amino acid variations at the recited position in the polypeptide sequence of SEQ ID NO:2 are further disclosed. The detailed disclosure contained in Applicants' specification (as substantiated by the disclosure of three polypeptide sequences and 11 other clonal variants) provides a detailed description of the structure/activity of the claimed variant sequences and fragments. See also, the sequence listing page and the tables. The biological activities of such polypeptide molecules, for example, with respect to their reactivity to IgE molecules, are further discussed in the Examples section. See, the disclosure in Fig. 5 and the description thereof at page 6 of the present application. As such, the specification provides an enabling disclosure of the claimed polypeptide fragments, and immunogenic activity thereof. The entire genus of Applicants' claimed polypeptide fragments could be routinely generated, for example, using the recombinant preparative schemes described by the present specification. Such fragments could be further tested, for example, with respect to binding to monoclonal antibodies (Fig. 4) and/or IgE reactivity (Fig. 5). The whole process would constitute nothing beyond what is routine in the art.

. Claims directed to the pharmaceutical composition/vaccines

In the paragraphs bridging pages 11 and 12, the Office Action alleges that the pharmaceutical compositions and/or vaccines of the present invention are non-enabled. This contention is respectfully traversed.

Applicants' specification, coupled with a skilled worker's knowledge, provides more than adequate guidance on how to make the claimed polypeptide molecules and use pharmaceutical compositions and medicaments comprising such polypeptides for immunotherapy. The specification provides both general and specific guidance regarding the specific epitopes in allergens and how such could be manipulated for reliable hyposensitisation. See, for example, the disclosure contained in the paragraphs bridging [0031]-[033] of the published specification and the reference article by Schramm et al., 1999, *J. Immunol.* 162: 2406-2414. With respect to DNA vaccines, the specification explicitly teaches that "experimental evidence of allergen- specific influencing of the immune response has been furnished in rodents by injection of allergen-encoding DNA (Hsu et al., 1996, *Nature Medicine* 2 (5): 540-544)." Furthermore, the specification of the present application discloses specific immunotherapy or desensitization as therapeutic field for especially recombinant allergen proteins with higher purity and therefore reduced side effects than allergen proteins isolated from natural sources which are always mixtures of compounds. To this end, the specification discloses strategies to minimize the risks of side effects with the development of T-cell reactive fragments with reduced or no IgE- reactivity leading to hypoallergenic peptides (see, the section bridging paragraphs [0063]-[0067] of the published specification). The screening for T-cell and IgE epitopes were common knowledge at the priority date of the present application. Thus, a person skilled in the art would have been able to identify T-cell and IgE epitopes and produce hypoallergenic peptides. Nevertheless, also the classic approaches of specific immunotherapy and desensitization were applicable as a skilled person would have known the pharmaceutical effects and also the side effects and risks of an

allergen protein administered to a patient and would have followed clinical recommendation protocols for specific immunotherapy and desensitization.

In relation to an enabling disclosure on the utilization of grass pollen allergen polypeptides in treatment of subjects, the specification provides a detailed disclosure for the design, synthesis and use of recombinant allergen extracts with reduced IgE reactivity. See, for example, the disclosure contained in Figs. 4 and 5. To this end, the Examiner is also courteously invited to review the disclosure contained in Focke et al. (Focke et al., *FASEBJourval,* 15, 2042- 44, 2001), a copy of which is enclosed herewith. As evidenced by the disclosure in the "Principle Findings" section of Focke and the immunoglobulin reactivity data provided in Table 1, it is respectfully submitted that as of the filing date of the present application, the instantly claimed grass pollen allergens could be routinely manipulated and utilized as pharmaceutical preparations in a manner recited in the claims.

Thus it is respectfully submitted that the specification provides an enabling disclosure on the claimed allergenic properties of the recombinant, *Phleum pratense* allergen polypeptides of the instant invention. Therefore, the specification's express teaching that the claimed compounds are pharmaceutically useful is clearly credible as required. The PTO's contentions regarding non-enablement are especially weak in view of the detailed disclosure contained in Applicants' own specification and the state of the art before the earliest filing date of the instant application. Withdrawal of the rejection is respectfully requested.

To support the contention of non-enablement, the Office Action cites Tarzi *(Expert Opinion in Biol. Thea,* 2003) to allege that whole allergen immunotherapy is unpredictable. However, even Tarzi discloses the therapy of allergic diseases with specific immunotherapy or desensitization in general being effective and successfully applied for many years. See, the last paragraph at page 617 of the cited reference. Moreover, in Gefter et al. (USP 6,795,234) discloses that the risk of systemic reactions like anaphylactic shock can be effectively minimized in individuals via specific immunotherapy, wherein pharmaceutical compositions comprising allergen polypeptides and/or vaccines comprising DNA sequences which encode such polypeptide allergens are utilized. See, the complete third and fourth paragraphs in the 'BACKGROUND OF THE INETNION" (especially, col. 1, lines 26-45) of Gefter's USP '234. As such, the PTO's contentions of non-enablement, based on the disclosure contained in Tarzi is without merit.

The final Office Action at page 6 alleges that it would 'take undue trials and errors to practice the claimed invention." These allegations, however, do not present any evidence to doubt the objective enablement of Appellants' disclosure. As clearly and succinctly stated by the court in In *reMarzocchi,* 169 USPQ 367, 369 (CCPA 1971):

As a matter of Patent Office practice, then a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph of 5112, unless there is reason to doubt the objective truth of statements contained therein relied on for enabling support. (emphasis in original)

Furthermore, as stated in *Marzocchi,* at 370, the PTO must have adequate support (evidence or reasoning) for its challenge to the credibility of Appellants' statements of enablement. Thus, in the absence of evidence which demonstrates otherwise, the claims must be taken to satisfy the requirements of 35 U.S.C. 5 112, ¶1.

Working examples are not required to establish enablement. As stated by the court *Marzocchi,* at page 369:

The first paragraph of 5112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

> The assertion of undue experimentation in the rejection is merely conclusory. Further, as discussed above, the specification provides more than sufficient guidance to make and use the claimed medicaments and/or pharmaceutical compositions using no more than routine experimentation. Finally, a high level of skill does not establish that one skilled in the art would have reasons to doubt the veracity of the statements in Appellants' specification with respect to the use of the claimed composition in the diagnosis, treatment, and/or prevention of the claimed conditions.
>
> Based on the aforementioned remarks and arguments, further in view of the amendments presented herein, it is respectfully submitted that Applicants' specification provides an enabling disclosure of what is claimed by the present invention. Withdrawal of the rejection under 35 U.S.C. 5112, ¶1, is respectfully requested.
>
> In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below."

The specification does not provide support for any polypeptide fragment which "comprises" a partial sequence of 50 to 350 amino acids, amino acids 1-200 or amino acids 185-500 of the recited sequences. The term 'comprises' is open language which opens the claim up to encompass an enormous number of undisclosed fragments which may include sequence added onto the N-and/or C-terminus that is unrelated to the polypeptides of SEQ ID NO:2, 4 or 6 or the variants of SEQ ID NO:2 in clones 1-11. The limitations of "an immunomodulatory, T-cell-reactive polypeptide fragment" of claim implies that the immune system is changed, but no specific changes are recited. Therefore, the term 'immunomodulatory' encompasses just about any reaction by any cells or pathways related to the immune system. In the same way, the term 'T-cell reactive' is largely undefined. Any fragment or processed subsequence of the fragment that induces any T cell response or interaction is encompassed by the instant claims. Without a recitation for a specific function of peptides which "comprise" the recited fragments, one of ordinary skill in the art would not be able to screen for peptides that possess the requisite function and which could be made and used in the claimed invention. Applicant's argument that the fragments could be further tested, for example, with respect to binding to monoclonal

antibodies and/or IgE reactivity and that the whole process would constitute nothing beyond what is routine in the art and that the screening for T-cell and IgE epitopes were common knowledge at the priority date of the present application and a person skilled in the art would have been able to identify T-cell and IgE epitopes and produce hypoallergenic peptides is not persuasive. Without a recitation for the testable function in the claim, one of ordinary skill in the art would not be able to test the peptides for requisite activity to determine the genus of peptides encompassed for use in the claimed invention.

It is the Examiner's position that when a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that use. See MPEP 2164.01(c). Following the guidance from the MPEP, for the claim to be enabled, the specification must teach how to make the claimed composition without undue experimentation and must teach how to use the composition for at least one pharmaceutical use without undue experimentation. To enable a pharmaceutical use for a substance, the specification must teach how to use the substance, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure a disease in the animal to which the substance is administered. When applicant is claiming a pharmaceutical composition, applicant must enable a pharmaceutical use. This rejection could be overcome by deleting the words "pharmaceutical" from the claim as when no use is recited in a claim, any enabled use will suffice.

The claims, as recited, include the use of SEQ ID NOs: 2, 4, or 6, the variants of SEQ ID NO:2 in clones 1-11, any polypeptide comprising amino acids 1-200, amino acids 185-500 and any 50 to 350 amino acid long peptide from SEQ ID NO: 2, 4, 6 or the variants of SEQ ID NO:2

in clones 1-11. It is well known in the art that even small changes can affect the binding specificity of an antibody. Colman *et al.* (PTO-892 mails on 09/25/2009; Reference U) teaches that single amino acid changes in an antigen can effectively abolish antibody antigen binding. Abaza et al. in (PTO-892 mailed on 09/25/2009; Reference V) teaches that single amino acid substitutions that are outside the antigenic site on a protein effect antibody binding. Further, Lederman *et al.* (PTO-892 mailed on 09/25/2009; Reference W) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document). In addition, Blumenthal et al. teaches that correlations between structure and IgE binding (or the lack of IgE binding) cannot be predicted on an a priori structural basis (PTO-892 mailed on 09/25/2009, Reference X, see entire document and page 39 of third full paragraph). Kinnunen et al. (PTO-892 mailed on 09/25/2009 page 2, Reference U, abstract, discussion) teaches that the use of allergen peptide derivatives or "altered peptide ligands" of the lipocalin allergen. The reference teaches that APL induce differential T cell stimulation (In particular, Table I, page 6, paragraph spanning left and right columns). The discussion cautions those who are looking to use APL in immunotherapy for allergy because some T cells populations, such as pathogenic memory cells, that are induced by certain APL would exacerbate allergic disease (In particular, page 7, left column, second paragraph). One of ordinary skill in the art would be required to determine how alterations to each position of the peptide affect binding to MHC and how that in turn effects T cell activation. The T cell activation induced by the peptide in vivo would need to promote hypoallergenic/ tolerogenic effects, which is also highly unpredictable. The specification has not adequately disclosed the genus of polypeptide fragments which comprise fragments of allergens and allergen variants to be used to treat allergy. The aforementioned

unpredictibility in the art highlights that an undue amount of experimentation is necessary to practice the claimed invention.

Therefore, for all the reasons stated *supra*, it remains at issue is whether or not the claimed compositions would function as a 'pharmaceutical composition.' In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition or vaccine as claimed, absence of working examples providing evidence which is reasonably predictive that the claimed pharmaceutical compositions are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success.

The Examiner does not know why Applicant is arguing about DNA vaccines, as the claims do not in any way encompass DNA vaccines.

Applicant's argument that Focke et al.(Focke et al., *FASEB Jourval,* 15, 2042- 44, 2001), teaches that the instantly claimed grass pollen allergens could be routinely manipulated and utilized as pharmaceutical preparations in a manner recited in the claims is confusing and not persuasive. First, Focke et al. is directed to Phl p1, not Phl p 4 as presently claimed so the Examiner is not sure why Applicant stated that it is directed to the instantly claimed grass pollen allergens. Further, the reference teaches in vitro and in vivo skin assays using 28-32 amino acid long peptides of Phl p 1. The reference does not teach using longer peptides as claimed, nor does the reference teach using peptides that comprise non-allergen amino acids on their N- and/or C-terminus as the claims encompassed by the instant claim recitations. This reference would be persuasive to show that small peptides consisting of a recited sequence that have the function of

being able to generate protective IgG antibodies that inhibit the binding of IgE to the native allergen for pharmaceutical use. However, the instant claims are not directed to what is routine in the art of Focke et al.

Applicant's assertion that that the assertion of undue experimentation is merely conclusory is not persuasive. The Examiner has provided sufficient reasoning to question the enablement set forth in the specification for the genus of peptides and pharmaceutical compositions encompassed. The claims with "comprising" language that read on less than full length require a recitation of a testable function. The Examiner has shown above and in previous Office Actions that protein function and IgE binding are impacted by structure and that one cannot predict how changes in structure will alter antibody binding and protein function. As such, using the genus of peptides encompassed in a pharmaceutical composition to treat allergy is unpredictable and would require one of ordinary skill in the art to perform undue experimentation to practice the invention commensurate in scope with the claims. Accordingly, the rejection of claims 21-22 and 30-31 is maintained.

7. Claim 21 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of : recombinant, isolated polypeptides of SEQ ID NO: 2, 4, 6 encoded by SEQ ID NO:1, 3 or 5, respectively, the variants of SEQ ID NO:2 in clones 1-11, the polypeptide fragments 1-200 and 185-500 thereof and a composition thereof

Applicant is not in possession of : an **immunomodulatory, T-cell-reactive polypeptide fragment which comprises a partial sequence of 50 to 350 amino acids** of the polypeptide sequence (set forth in of claim 13) of claim 21 for the same reasons as set forth in the Office Action mailed on 09/25/2009.

Applicant's arguments filed on 12/28/2009 have been fully considered, but are not found persuasive.

Applicant argues that the claims satisfy the New Written Description Guidelines, particularly Examples 5 and 12:

> Likewise, in the instant application, all the relevant characteristics of the rPhi p 1 variants and fragments thereof are provided in the specification. For example, the sequences of clones 1-12 of SEQ ID NO: 2 can at once be obtained by performing amino acid substitutions and/or insertions at the recited positions of the native sequence of SEQ ID NO: 2. The variants thus produced can be assayed for immunogenic and T-cell reactive activity using the methods described in the Examples (e.g., binding to monoclonal antibodies). Similarly, N-terminal fragments of each of the variants comprising the first 200 amino acids or C-terminal fragments of each of the variants comprising the last 316 amino acids (i.e., amino acids 185-500) can be generated using the techniques described in the Examples. Thus the structural information of six fragment sequences of the native allergens (i.e., N-terminal and C-terminal fragments of SEQ ID NOs: 2, 4, and 6) and 24 fragments from variant allergens (i.e., N-terminal and C- terminal fragments of clones 1-12 of SEQ ID NO: 2) are explicitly taught by the instant application. Other representative examples of such fragment sequences, for example, Pl-P6 (SEQ ID NOs: 27-32) obtained from the amino acid sequencing of the purified and fragmented Phi p 4 allergens are additionally described in the instant application.
>
> The PTO's contention that the disclosure of specific examples of rPhi p 4 polypeptide sequences, i.e., SEQ ID NOs: 2, 4, or 6, fails to provide adequate written description for the genus of the claimed polypeptides is respectfully traversed. Firstly, this is different from *University of Califonia v. Lilly,* 964 F.2d 1128 (Fed. Cir. 1997) or *Universi/y of Rochester v. Searle,* 358 F.3d 1303 (Fed. Cir. 2004) where functional language was involved with insufficient structural details available for a chemical compound. These facts here are similar to those in *Capon v. Eshhar,* 76 USPQ2d 1078, 1082 (Fed. Cir. 2005) and *Halkner v. Inglis,* 448 F.3d 1357 (Fed.Cir. 2006). In these cases, the court held that even where there are no examples within the scope of a claimed genus, a written description exists where the elements of the members of the genus are known. Here, based on the complete disclosed rPhlp 4 sequences (e.g., SEQ ID NOs: 2, 4, and 6), variant sequences are *also* comprehensible without explicitly listing each and every sequence. The specification provides representative examples of polypeptides, for example, clones 1-12 of SEQ ID NO: 2. Furthermore, in view of the detailed level of knowledge in molecular biology and the sophisticated tools available to the skilled worker, *any* fragment sequence which meets the claimed structural (i.e., amino acid sequence) can be can be generated. For example, the sequences can be generated

using recombinant preparative methods or enzymatic digestion of the native sequence. Additionally, functional features (e.g., immunogenic activity) of these fragments and variants can be routinely tested. Explicit description is therefore not necessary.

"Likewise, in the instant application, insofar as the complete structures of the claimed polypeptides and variants thereof are provided by the originally-filed specification, the structure of all possible fragment polypeptides can be predicted from the full-length putative sequences. This applies equally well to the claimed fragment sequences of 200 amino acids or 316 amino acids of SEQ ID NO: 2. To hold the subject matter of the present claims as lacking adequate written description would be contrary to the agency's own published guidelines. Withdrawal of the rejection is respectfully requested. "

It is the Examiner's position that to satisfy the Written Description requirement, Applicant must describe a correlation between the structure and the function. If no function is recited in the claims (as in claim 22), then it is *possible* that the claims satisfy the written description requirement, while not satisfying the enablement requirement which requires the recitation of a testable function in order to make and use.

It remains the Examiner's position that the specification has not adequately disclosed the genus of polypeptide variants fragment comprises a partial sequence of the disclosed polypeptides wherein the polypeptide fragments have a function (immunomodulatory and T-cell reactive). It remains the Examiner's position that the specification does not disclose a correlation between the structure of the allergens, variants and fragments thereof and function ("immunomodulatory, T-cell-reactive" of claim 21) such that a skilled artisan would have known what allergen variants and fragments of the Phl p 4 allergens attain the claimed functions. "Possession may not be shown by merely describing how to obtain possession of member of the claimed genus or how to identify their common structural features" *Ex parte Kubin* (83 U.S.P.Q.2d 1410 (BPAI 2007)), at page 16. "Without a correlation between structure and function, the claim does little more than define the claimed invention by function" *supra*, at page

17. Definition by function does not suffice to define the genus because it is only an indication of what the allergen does and what functional properties it has, rather than what it is.

Accordingly, the rejection of claim 21 is maintained.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 13, 15, 21-22, 26, 30-31, 33 and 35-36 stand rejected under 35 U.S.C. 102(b) as being anticipated by Suck et al. (Reference 1; IDS filed 12/23/2004) for the same reasons as set forth in the Office Action mailed on 09/25/2009.

It is noted that the previous action stated that the reference was Reference 4 on the IDS filed on 12/23/2004, but it is actually Reference 1. Accordingly, this Office Action is a Non-final Office Action.

Suck et al teaches isolated Phl p 4 from Phleum pratense in a pharmaceutically acceptable carrier (water) (In particular, Figures 1-5, whole document).

The recitations of "which comprises the polypeptide sequence set forth in SEQ ID NO: 2, SEQ ID NO: 4 or SEQ ID NO: 6" and "which is encoded by a the polynucleotide sequence is

set forth in SEQ ID NO: 1, SEQ ID NO: 3 or SEQ ID NO: 5" of claim 13; "comprises a partial sequence of 50 to 350 amino acids of the polypeptide" of SEQ ID NO:2 SEQ ID NO:4 or SEQ ID NO:6 of claim 21; which comprises "amino acids 1-200 of the polypeptide" or "amino acids 185-500 of the polypeptide" of SEQ ID NO:2 SEQ ID NO:4 or SEQ ID NO:6 of claim 22; and which "comprises (a) a polypeptide which is encoded by single nucleotide polymorph of a polynucleotide whose sequence is set forth in SEQ ID NO: 1, (b) a single amino acid polymorph of a polypeptide whose sequence is set forth in SEQ ID NO: 2" of claim 33 is inherent. The reference Phl p 4 molecule is the same as the protein of claims. Further characterization of a known compound does not make it patentably distinct. See Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art."

The recitations of "an immunomodulatory, T-cell-reactive polypeptide fragment which comprises a partial sequence of 50 to 350 amino acids" of claim 21 is inherent. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced Phl p 4 allergen. Products of identical chemical composition cannot have mutually exclusive properties because a chemical composition and its properties are inseparable. Therefore, if the

prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Claim 35 is included in this rejection because the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113. Further, once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process.

It is noted in the specification discloses on page 14 that there are three natural isoforms of the heterogenous Phl p 4 allergen molecule (SEQ ID NOs 2, 4 and 6). Since the office does not have a laboratory to test the reference Phl p 4 allergen, it is applicant's burden to show that the reference allergen does not comprise the amino acid sequences of SEQ ID NO:2, 4 and 6 recited in the claims. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

Applicant's arguments filed on 12/28/2009 have been fully considered, but are not found persuasive.

Applicant argues:

"With respect to Suck et al. *(Clinical & ExperimentalAllelgy,* 2000), Applicants submit that the reference pertains to Phi p 13, another allergen of *Phleum pretense.* With respect to the disclosure in Fahibusch et al. *(Clinical & Experimental Allergy,* 1998) and the ~102(b) rejection based thereon, the Examiner's allegations are respectfully traversed. Based on the Examiner's rationale at pages 17-18 of the Office Action, it appears that this rejection is based on the cited references' disclosure of the term Phi p 4 polypeptide. The Examiner is alleging that the references' teaching of Phi pl protein creates a presumption of structural identity. This contention lacks scientific merit. To this end, a search with the term *'Phleum pretense* 'Phi p 1"' in NCBI identifies at least 5 hits, of which 4 accession numbers are directed to Phl pl (or Phi p I) polypeptides. Three accession numbers relate to polypeptides that are 262-263 amino acids. One accession number relates to a shorter sequence, which was not further analyzed (accession **No.:** CAG24374; a protein of 240 amino acids). Multiple sequence alignment of these sequences using CLUSTAL (program freely available via EXPASY) reveals three variant sequences. See the enclosed Exhibit B. Therefore, at least three other sequences are recognized by the same name, i.e., Phl pl. More importantly, none of the identified sequences met the structural features of the instantly claimed polypeptides (i.e., length of -500 amino acid residues). As such, the polypeptides of the instant application are novel over what is taught by the prior art.

It is by now well-established that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See MPEP 52131 and further corroborated by the Fed. Circuit's decision in *VerdegaalBros. v. Union OilCo. of Cal#brvia,* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). With respect to inherency, the Courts have established that "the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."' *In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Inasmuch as the cited Suck et al. and Fahibush et al. say nothing about Phl p 4 polypeptide sequences and the art (or the Examiner) has not established that the Phi p 4 polypeptide disclosed therein necessarily comprises the sequences recited herein, the rejection is without legal merit.

With respect to the PTO's contention that sequences need not be provided, the controlling case law dictates that for anticipation, "the identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The Office Action fails to establish that the polypeptides disclosed in the aforementioned references contain the complete Phl p 4 polypeptide sequence as presently claimed. To this end, the enclosed Exhibit B unequivocally demonstrates that it cannot be ascertained whether the references teach a sequence that is completely identical to what is claimed in the present application. More importantly, it is clear to those skilled in the art that none of the cited references of Suck et al. and Fahibusch et al. provide "a complete detail" (i.e., the polypeptide sequence) of the claimed invention. As such, an inherency rejection under ~102/~103 is not supported and should be withdrawn. See MPEP 52112.

Moreover, the Examiner has given no basis for alleging that it would be "reasonable" to assume that the references' products are the same as those claimed herein. See *Is re Best* 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). If anything, the record summarized above shows such as assumption to be unreasonable. Thus, the burden remains on the Examiner. Withdrawal of the rejection is respectfully requested.

Claims directed to recombinant polypeptides

In view of Applicants' own disclosure, for example, Fig. 4 of the instant specification, it is clear that the recombinant polypeptides of the instant invention are different and thus novel over the natural Phl p

> 4 polypeptides. Therein, it is expressly disclosed that nPhl p 4 has a higher molecular weight than r Phl 4 of the instant invention. Favorable reconsideration is respectfully requested.."

Contrary to Applicant's assertion, this rejection is not based on the term Phl p 4. It is based upon isolated Phl p 4 on a gel in Figures 1-5 and the recitation that the protein bands are Phl p 4 (In particular, Figures 1-5, whole document). It is noted that 3 of the authors of the Suck et al. reference are inventors in the instant Application. The Examiner does not know why Applicant is arguing about the sequence of Phl p 1 as that does not have any relevance to the instant claims which are directed to Phl p 4. Contrary to Applicant's assertion, the sequence does not need to be provided to anticipate the claimed invention. Applicant has not shown by any type of evidence that the reference Phl p 4 is not the Phl p 4 of SEQ ID NOs 2, 4 or 6. Exhibit B does not provide any evidence to the Examiner other than to say that Applicant cannot prove that the reference Phl p 4 is not SEQ ID NOs 2, 4 or 6. As has been stated in all of the previous Office Actions, Suck et al. need not teach the polypeptide sequence to anticipate the instant claims. Further characterization of a known compound does not make it patentably distinct. See Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art."

Therefore, it remains Applicant's burden to prove that the reference Phl p 4 molecule, which was isolated from the same source by 3 of the instant inventors as the claimed Phl p 4

allergen, does not have the sequence of SEQ ID NO:2, 4 or 6. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Accordingly, the rejection is maintained.

10. Claims 13, 15, 21-22, 26, 30-31, 33 and 35-36 stand rejected under 35 U.S.C. 102(b) as being anticipated by Fahlbusch et al. (Reference 3; IDS filed on 12/23/2004) for the same reasons as set forth in the Office Action mailed on 09/25/2009.

Fahlbusch et al teaches isolated Phl p 4 from Phleum pratense in a pharmaceutically acceptable carrier (water) (In particular, 'Methods' section; paragraph spanning pages 801-802, Figure 1; whole document).

The recitations of "which comprises the polypeptide sequence set forth in SEQ ID NO: 2, SEQ ID NO: 4 or SEQ ID NO: 6" and "which is encoded by a the polynucleotide sequence is set forth in SEQ ID NO: 1, SEQ ID NO: 3 or SEQ ID NO: 5" of claim 13; "comprises a partial sequence of 50 to 350 amino acids of the polypeptide" of SEQ ID NO:2 SEQ ID NO:4 or SEQ ID NO:6 of claim 21; which comprises "amino acids 1-200 of the polypeptide" or "amino acids 185-500 of the polypeptide" of SEQ ID NO:2 SEQ ID NO:4 or SEQ ID NO:6 of claim 22; which "comprises (a) a polypeptide which is encoded by single nucleotide polymorph of a

polynucleotide whose sequence is set forth in SEQ ID NO: 1, (b) a single amino acid polymorph of a polypeptide whose sequence is set forth in SEQ ID NO: 2" of claim 33 is inherent. The reference Phl p 4 molecule is the same as the protein of claims. Further characterization of a known compound does not make it patentably distinct. See Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art."

The recitations of "an immunomodulatory, T-cell-reactive polypeptide fragment which comprises a partial sequence of 50 to 350 amino acids" of claim 21 is inherent. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced Phl p 4 allergen. Products of identical chemical composition cannot have mutually exclusive properties because a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in

the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Claim 35 is included in this rejection because the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See MPEP 2113. Further, once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process.

It is noted in the specification on page 14 that there are three natural isoforms of the heterogenous Phl p 4 allergen molecule (SEQ ID NOs 2, 4 and 6). Since the office does not have a laboratory to test the reference Phl p 4 allergen, it is applicant's burden to show that the reference allergen does not comprise the amino acid sequences of SEQ ID NO:2, 4 and 6 recited in the claims. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

Applicant's arguments filed on 12/28/2009 have been fully considered, but are not found persuasive.

Applicant argues:

> "With respect to Suck et al. *(Clinical & ExperimentalAllelgy,* 2000), Applicants submit that the reference pertains to Phi p 13, another allergen of *Phleum pretense.* With respect to the disclosure in Fahibusch et al. *(Clinical & Experimental Allergy,* 1998) and the ~102(b) rejection based thereon, the Examiner's allegations are respectfully traversed. Based on the Examiner's rationale at pages 17-18 of the Office Action, it appears that this rejection is based on the cited references' disclosure of the term Phi p 4 polypeptide. The Examiner is alleging that the references' teaching of Phi pl protein creates a presumption of structural identity. This contention lacks scientific merit. To this end, a search with the term *'Phleum*

pretense 'Phi p 1'" in NCBI identifies at least 5 hits, of which 4 accession numbers are directed to Phl pl (or Phi p I) polypeptides. Three accession numbers relate to polypeptides that are 262-263 amino acids. One accession number relates to a shorter sequence, which was not further analyzed (accession **No.:** CAG24374; a protein of 240 amino acids). Multiple sequence alignment of these sequences using CLUSTAL (program freely available via EXPASY) reveals three variant sequences. See the enclosed Exhibit B. Therefore, at least three other sequences are recognized by the same name, i.e., Phl pl. More importantly, none of the identified sequences met the structural features of the instantly claimed polypeptides (i.e., length of -500 amino acid residues). As such, the polypeptides of the instant application are novel over what is taught by the prior art.

It is by now well-established that "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See MPEP 52131 and further corroborated by the Fed. Circuit's decision in *VerdegaalBros. v. Union OilCo. of Cal#brvia,* 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). With respect to inherency, the Courts have established that "the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."' *In re Robertson,* 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Inasmuch as the cited Suck et al. and Fahibush et al. say nothing about Phl p 4 polypeptide sequences and the art (or the Examiner) has not established that the Phi p 4 polypeptide disclosed therein necessarily comprises the sequences recited herein, the rejection is without legal merit.

With respect to the PTO's contention that sequences need not be provided, the controlling case law dictates that for anticipation, "the identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.,* 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The Office Action fails to establish that the polypeptides disclosed in the aforementioned references contain the complete Phl p 4 polypeptide sequence as presently claimed. To this end, the enclosed Exhibit B unequivocally demonstrates that it cannot be ascertained whether the references teach a sequence that is completely identical to what is claimed in the present application. More importantly, it is clear to those skilled in the art that none of the cited references of Suck et al. and Fahibusch et al. provide "a complete detail" (i.e., the polypeptide sequence) of the claimed invention. As such, an inherency rejection under ~102/~103 is not supported and should be withdrawn. See MPEP 52112.

Moreover, the Examiner has given no basis for alleging that it would be "reasonable" to assume that the references' products are the same as those claimed herein. See *Is re Best* 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). If anything, the record summarized above shows such as assumption to be unreasonable. Thus, the burden remains on the Examiner. Withdrawal of the rejection is respectfully requested.

Claims directed to recombinant polypeptides

In view of Applicants' own disclosure, for example, Fig. 4 of the instant specification, it is clear that the recombinant polypeptides of the instant invention are different and thus novel over the natural Phl p 4 polypeptides. Therein, it is expressly disclosed that nPhl p 4 has a higher molecular weight than r Phl 4 of the instant invention. Favorable reconsideration is respectfully requested.."

Contrary to Applicant's assertion, this rejection is not based on the term Phl p 4. It is based upon isolated Phl p 4 on a gel and purification of the Phl p 4 allergen from an extract (In

particular, 'Methods' section; paragraph spanning pages 801-802, Figure 1; whole document). It is noted that 2 of the authors of the Fahlbusch et al. reference are inventors in the instant Application. The Examiner does not know why Applicant is arguing about the sequence of Phl p 1 as that does not have any relevance to the instant claims which are directed to Phl p 4. Contrary to Applicant's assertion, the sequence does not need to be provided to anticipate the claimed invention. Applicant has not shown by any type of evidence that the reference Phl p 4 is not the Phl p 4 of SEQ ID NOs 2, 4 or 6. Exhibit B does not provide any evidence to the Examiner other than to say that Applicant cannot prove that the reference Phl p 4 is not SEQ ID NOs 2, 4 or 6. As has been stated in all of the previous Office Actions, Fahlbusch et al. need not teach the polypeptide sequence to anticipate the instant claims. Further characterization of a known compound does not make it patentably distinct. See Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. " The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art."

Therefore, it remains Applicant's burden to prove that the reference Phl p 4 molecule, which was isolated from the same source by 2 of the instant inventors as the claimed Phl p 4 allergen, does not have the sequence of SEQ ID NO:2, 4 or 6. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the

claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Accordingly, the rejection is maintained.

11. Claims 13, 15, 21-22, 26, 30-31, 33 and 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Suck et al. (Reference **4**; IDS filed 12/23/2004).

Suck et al teaches isolated Phl p 4 from Phleum pratense (In particular, Figures 1, 3-4, paragraph spanning pages 326-328 and 328-329, whole document).

The recitations of "which comprises the polypeptide sequence set forth in SEQ ID NO: 2, SEQ ID NO: 4 or SEQ ID NO: 6" and "which is encoded by a the polynucleotide sequence is set forth in SEQ ID NO: 1, SEQ ID NO: 3 or SEQ ID NO: 5" of claim 13; "comprises a partial sequence of 50 to 350 amino acids of the polypeptide" of SEQ ID NO:2 SEQ ID NO:4 or SEQ ID NO:6 of claim 21; which comprises "amino acids 1-200 of the polypeptide" or "amino acids 185-500 of the polypeptide" of SEQ ID NO:2 SEQ ID NO:4 or SEQ ID NO:6 of claim 22; and which "comprises (a) a polypeptide which is encoded by single nucleotide polymorph of a polynucleotide whose sequence is set forth in SEQ ID NO: 1, (b) a single amino acid polymorph of a polypeptide whose sequence is set forth in SEQ ID NO: 2" of claim 33 is inherent. The reference Phl p 4 molecule is the same as the protein of claims. Further characterization of a known compound does not make it patentably distinct. See Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999) "Artisans of ordinary skill may not recognize the inherent

characteristics or functioning of the prior art... However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art."

The recitations of "an immunomodulatory, T-cell-reactive polypeptide fragment which comprises a partial sequence of 50 to 350 amino acids" of claim 21 is inherent. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced Phl p 4 allergen. Products of identical chemical composition cannot have mutually exclusive properties because a chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Claim 35 is included in this rejection because the patentability of a product does not depend on its method of production. In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985) See

MPEP 2113. Further, once a product is fully disclosed in the art, future claims to that same product are precluded, even if that product is claimed as made by a new process.

It is noted in the specification discloses on page 14 that there are three natural isoforms of the heterogenous Phl p 4 allergen molecule (SEQ ID NOs 2, 4 and 6). Since the office does not have a laboratory to test the reference Phl p 4 allergen, it is applicant's burden to show that the reference allergen does not comprise the amino acid sequences of SEQ ID NO:2, 4 and 6 recited in the claims. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 26, 2010

Nora M. Rooney
Patent Examiner
Technology Center 1600

/Nora M Rooney/

Examiner, Art Unit 1644